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DAVID W HIBLER
WILLIAMS MORGAN & AMERSON P C
7676 HILLMONT
SUITE 250
HOUSTON, TX 77040

EXAMINER

LEFFERS JR, GERALD G

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/404,448

Applicant(s)

BYRNE, ET AL.

Examiner

Gerald G Leffers Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-43, 45-49, 61 and 63-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-43, 45-49, 61, 63-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 10/1/02 as Paper No. 21, in which several claims were cancelled (claims 44, 50-56, 58-60 and 62), several claims were amended (claims 41-43, 45-49, 57 and 61), and in which several new claims were added (claims 63-78). Claims 41-43, 45-49, 57, 61 and 63-78 are pending in this application.

Any rejection of record in the previous office action, Paper No. 18 mailed 3/26/02, that is not addressed in this action is withdrawn. This action is FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-43, 45-49, 57, 61, 63-78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is maintained for reasons of record in Paper No. 18 against claims 61-62. Applicant's arguments filed in Paper No. 21 have been fully considered but they are not persuasive.**

To summarize the rejection, these claims are drawn towards a specific recombinant HSV-1/AAV hybrid virus (rHSV d27.1rc) which is encompassed by the definition of biological material set forth in 37 C.F.R 1.801. Because it is apparent that this biological material is essential for practicing the claim invention, it must be obtainable by a reproducible method set

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forth in the specification or otherwise known and readily available to the public as detailed in 37 C.F.R. 1.801 through 1.809.

Response to Arguments

In response to this rejection in the previous action, applicants have submitted a statement of deposit indicating that the recited strain was deposited on 8/2/02 with the ATCC under the terms of the Budapest Treaty. However, the instant specification has not been amended to refer to the date of deposit, accession number, depository and address. In addition, there is no statement from applicant or applicants' representative concerning removal of restrictions upon allowance of claims drawn to the deposited strain. Applicants' attention is directed to the attachment mailed with this and the previous action concerning deposit requirements.

Claims 41-43, 45-49, 57, 63-78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This new rejection is necessitated by applicants' amendment of the claims in Paper No. 21.**

Each of the claims comprises the limitation "A recombinant herpes simplex viral vector that comprises a DNA segment isolated from herpes simplex virus deletion mutant ATCC PTA-4004, wherein said segment encodes an adeno associated virus cap gene and an adeno associated rep gene..." It is noted that applicants' response in Paper No. 21 does not point to the appropriate portion of the specification that provides support for the changes made to claim 41. There is, in fact, no literal support in the specification and claims as originally filed for the

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limitation that a segment is isolated from the specific clone HSV d27.1rc and comprised within a recombinant HSV viral vector. There are no working examples where this was done and no statement that this limitation is part of applicant's invention. Therefore, the newly added limitation is impermissible NEW MATTER.

Claims 73-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This new rejection is necessitated by applicants' amendment of the claims in Paper No. 21.**

Each of the claims is directed towards a composition comprising the HSV viral vector of the invention. The claims further comprise the limitation that the composition is "...formulated for administration" to a subject mammal or human. It is again noted that applicants' response in Paper No. 21 improperly does not point to those specific portions of the instant specification for support for formulating a composition comprising the HSV vector of the invention for administration to a subject mammal or human. In fact, the entire specification is directed towards using the HSV viral vector of the invention to produce rAAV vectors, which rAAV vectors are then formulated for administration to a subject. There is no support for using the HSV vector of the invention as part of a pharmaceutical composition to be administered to a subject mammal or human. Therefore, the cited limitation is impermissible NEW MATTER.

Examiner's Comments

It is noted that, because the instant specification does not address using the HSV vectors of the inventions directly for infecting humans (i.e. gene therapy), claims directed towards host cells comprising the HSV vectors/virions/particles of the invention are not rejectable under 35 U.S.C. 101 for being nonstatutory. If the instant specification did contemplate the use of the HSV vectors of the invention for direct infection of human cells in vivo, the claims directed to host cells comprising the HSV vectors would have been rejectable as improperly reading on cells within a human (i.e. as reading on the entire human).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
December 13, 2002

DAVID GUZO
PRIMARY EXAMINER


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SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

ATTACHMENT

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).
5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.